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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,155	12/27/2004	Imao Mikoshiba	Q85258	5395

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EXAMINER	
FINN, MEGHAN R	

ART UNIT	PAPER NUMBER
1609	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,155	MIKOSHIBA ET AL.	
	Examiner	Art Unit	
	Meghan Finn	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 27, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *February 08, 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The information disclosure statement filed December 27, 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The NPL reference from the Japanese Journal of Clinical Medicine was provided without a translation or an English language equivalent. As such its relevance cannot be determined and it has been placed in the application file, but the information referred to therein has not been considered.

Double Patenting

Claims 1-6, and 11-15 of this application conflict with claims 1-6, 12-14, and 19-20 of Application No. 10/519102. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of Application No. 10/519102. Although the conflicting claims are not identical, they are not patentably

distinct from each other because it is commonly known in the art that the best way of preventing diabetic complications is through glycemic control. Additionally, the two pharmaceutical compositions are identical, and despite their different intended uses, they are unpatentable over each other.

Claims 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-14, and 19-20 of copending Application No. 10/519102. Although the conflicting claims are not identical, they are not patentably distinct from each other because while claims 12-14, 19-20, and 11-15 are method claims and the intended use is an essential component of each claim, glycemic control inherently treats the progression of diabetes and diabetic complications. Since the composition to be used and the dosages are identical the intended use is the only point that differs in the claims, and thus the two methods are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohnota et al. (Novel Rapid- and Short-Acting Hypoglycemic Agent, a Calcium(2s)-2-benzyl-3-(cis-hexahydro-2-isoindolinylcarbonyl)Propionate(KAD-1229) That Acts on the Sulfonylurea Receptor: Comparison of Effects Between KAD-1229 and Gliclazide).

Claims 1-5, and 7-10 are a composition comprising mitiglinide and Ohnota et al. teaches a composition KAD-1229 (page 490, figure 1) that has the same structure as the mitiglinide calcium salt hydrate described as the applicant's preferred embodiment in the specification. KAD-1229 was a name used in early literature but it is referring to the same structure, figure 1 of Ohnota et al. is the exact same structure as that in the applicant's specification (page 5, line 1). Since claims 1-5, 7-10 are composition claims wherein the composition comprises mitiglinide, Ohnota et al. has anticipated the applicant's claims for a composition comprising mitiglinide or a mitiglinide calcium salt hydrate.

Claims 11-12 are anticipated by Ohnota et al. as well. In addition to teaching a composition comprising mitiglinide as discussed supra, Ohnota et al. teaches use of the composition for treating diabetes and achieving better glycemic control than previously possible with previous alternative drugs(page 494, column 2, paragraph 2), and also teaches that the composition will be an effective agent for treating postprandial hyperglycemia (page494, column 1, paragraph 1). Both glycemic control and controlling postprandial hyperglycemia will inhibit the progression of diabetes and help prevent diabetic complications (page 490, column 1, paragraph 1). Claims 11-12 outline dosages to be used from 5-45mg, and Ohnota et al. also teaches dosages from 0.3 to

3.0 mg/kg (page 491, column 1, paragraph 1). If one uses an average individual weight of 120 lbs or 55kg, then the dosages outlined in Ohnota et all would be equivalent to 16-165mg. This falls within the dosage range outlined in claim 11 (5-45mg) and in claim 12 (5-22mg) thus Ohnota et al. anticipates these claims.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Ouchi et al. (WO 00/71117). EP 1179342 A1, also by Ouchi et al. is a 371 national stage entry of WO 00/71117 and is being used as the English equivalent of WO 00/71117 since the WO application is in Japanese. All references to page numbers will refer to EP 1179342A1.

Claim 6 is also a composition comprising mitiglinide, with the added limitation that the dissolution time is 20 minutes or less. Ouchi et al. teaches not only the composition (paragraph [0005], line 50) but also that said compound has a dissolution time well under 20 minutes according to the same test, the first fluid of Japanese Pharmacopoeia (Paragraph [0010], line 30). Thus claim 6 is anticipated by Ouchi et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 13 is rejected under 35 U.S.C. 103(a) as being obvious over Ohnota et al. in view of Ouchi et al. (WO 00/71117 or EP 1179342A1).

In claim 13 the applicant specifies dosages of 10-11mg if mitiglinide calcium salt hydrate. As discussed above, Ohnota et al. anticipates the applicant's invention for dosages between 16-165mg. Ohnota et al. does fail to specifically teach the usefulness of mitiglinide with a dosage of 10-11mg, but, as it is well known in the art, it is always desirable to use smaller mg/kg dosages to mitigate side effects, so it would be obvious to use a lower range and 10mg would be an obvious dosage variant from the 16mg described in Ohnota et al. Additionally, Ouchi et al. teaches a composition for mitiglinide calcium salt hydrate from 5mg to 22mg for use in treatment of diabetes. So it would be obvious to one skilled in the art at the time the invention was made to modify the method of Ohnota et al. by administering a lower dosage such as that taught by Ouchi

et al. in order to have mitigated potential side effects. Thus use of 10-11mg such as described in claim 13 would be obvious over Ohnota et al.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landgraf et al. (A comparison of repaglinide and glibenclamide in the treatment of type 2 diabetic patients previously treated with sulphonylureas) in view of Ohnota et al. and Evans et al. (Recent Developments and Emerging Therapies for Type 2 Diabetes Mellitus).

In claims 14-15 the method is the same as that in claim 11 except it additionally involves treating patients with mitiglinide 3 times a day for 4 weeks or more. Ohnota teaches all the limitations of claim 11 and Landgraf et al. teaches the use of repaglinide 3 times per day for 4 weeks or more (page 166, column 1) as an effective way to treat diabetes, control postprandial hyperglycemia, control glucose levels and help reduce risk of diabetic complications (page 165, column 2). Repaglinide is not chemically equivalent to mitiglinide, however Evans et al. (Drugs in R&D, 1999) teaches that they are both members of the meglitinide family of anti-diabetic drugs (page 78, section 3.2) and have that both repaglinide and mitiglinide have similar anti-postprandial hyperglycemic effects (page 87, section 4.1.2). It would be obvious to one skilled in the art at the time of the invention that therapies involving mitiglinide would be similar to repaglinide and one of the best things to try when developing a new therapy is what worked for a similar acting drug. Thus it would be obvious to take the teachings of Ohnota et al. and Landgraf et al. in view of Evans et al. and expect similar results for

mitiglinide when using the 3 times a day for 4 weeks therapy such as described in claims 14-15.

Conclusion

No claims are allowed.

The prior art references of (Ohnota, Ouchi, Landgraf, Evans, Yamaguchi, Wuthrich, Lecouve, Kitahara, and Makino) are cited as being relevant to the application and are provided to show the extent of knowledge in the art about mitiglinide as an anti-diabetic drug prior to the applicant's invention.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-

3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

MF

Meghan Finn

Ardin H Marschel 6/23/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER